IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Mardh	
Application No.: 09/678,357	
Filed: 10/4/2000	Group Art Unit: 1645
Title: Screening Method for Gastritis	Examiner: K.S. Shahnan Shah
Attorney Docket No.: SMAR.P-001	

BRIEF FOR APPELLANT

This brief is filed in support of Applicants' Appeal from the final rejection mailed 4/28/2005. Consideration of the application and reversal of the rejections are respectfully urged.

Real Party in Interest

The real parties in interest are the inventors.

Related Appeals and Interferences

To Applicants' knowledge, there are no related appeals or interferences.

Status of Claims

Claims 14, 15, 18-30 and 32 are rejected. Claims 1-13, 16, 17, 31 and 33-43 have been canceled. No other claims have been presented.

Status of Amendments

The response after final rejection has been entered.

Summary of Claimed Subject Matter

The present invention relates to a method for diagnosing possible presence of gastritis in a human by evaluating a blood sample. (Page 4, lines 22-23). In the method, the sample is tested for the presence of antibodies specific for H,K-ATPase, antibodies specific for Helicobacter pylori, and the concentration of pepsinogen I, and comparing the results of these assays to the respective values of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen concentration of a normal population. (Page 4, lines 23-29). As part of this comparison, an indicator number is calculated by multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies, and then compared to a similarly calculated number from a normal mammal of the same species. (Page 5, lines 15-18, Page 8, lines 5-7, Page 9, lines 20-22; Page 15, lines 9-18) The levels of H,K-ATPase antibodies, Helicobacter pylori antibodies, pepsinogen I concentration in the sample **and** the number obtained by multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies that are different from the respective values in the normal population allow diagnoses of conditions of the gastric mucosa that previously have required more costly, complicated invasive procedures, i.e. gastroscopy with histopathological examination of biopsies of the mucosa. (Page 8, lines 8-11).

Grounds of Rejection to be reviewed on Appeal

Claims 14, 15, 18-30 and 32 are rejected under 35 USC § 103(a) as obviuos over the combination of Oksanen and Ma.

Argument

MPEP § 2142 states that:

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

MPEP § 2143.03 continues:

> To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

By these standards, it is clear that the Examiner has failed to establish a *prima facie* case of obviousness in the present case.

In the present case, independent claim 14 contains a recitation of:

> the steps of multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies to get a number, and comparing the number to a number calculated similarly for the normal population.

This limitation is part of every claim in the application, yet at no time has the Examiner shown such a step as being taught in the art. Furthermore, the Examiner has offered no explanation of how performing a multiplication of these two numbers is suggested by the art.

In the Official Action mailed August 5, 2004, the Examiner stated that "limitation such as higher or lower level of indicators or calculating ratios of the indicators are being viewed as limitations of optimizing experimental parameters." (Page 5 and again on Page 6). This argument, however, has nothing to do with the claimed invention when then, as now, calls for multiplying two numbers together to provide a diagnostic indicator. Whether or not it is true that determination of a ratio between known experimental values may be generally obvious, nothing can be said without substantial specific explanation concerning the product of two values. A product is not a ratio, and does not generally provide the same type of information as a ratio. Specifically, a ratio says something about the relative amounts of two materials, a product does not. Thus, this argument fails to address why this limitation of the claims is taught or suggested by the art.

In the Advisory Action mailed January 5, 2006, the Examiner still does not address this limitation. Although the limitation of claim 14 and Applicants' argument concerning it are noted, the balance of the Examiner's argument is irrelevant to the question of whether this limitation is found or suggested in the art.

(1) The Examiner says that the art is capable of producing results that show varying levels of antibodies and pepsinogen. This is true; the cited art shows the individual tests. It does not, however, show a calculation of a diagnostic factor by multiplying two of the result.

(2) The Examiner also argues from case law that differences in concentration or temperature generally will not support patentability. Since this has nothing to do with the step at issue, the reasons for this statement are unclear. Furthermore, claim 14 does not include any limitations as to concentration or temperature. Other cited cases relate to ranges in molecular weights or molar proportions.

(3) The Examiner argues that a basis as to why optimization limitations fail to provide a basis for patentability has been presented. The Examiner has failed to say what limitation in the claims differs from the art as an optimization of a range, however. This is not a case where the art performs the multiplication step but identifies a different range of values as being diagnostic. The art does not show or suggest the multiplication step at all. Citation of case law is not a substitute for showing that the art actually teaches or suggests the limitations of the claims.

For these reasons, Applicants submit that the Examiner has failed to present a *prima facie* case of obviousness. The rejection under 35 USC § 103 should therefore be reversed.

Respectfully submitted,

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Claims Appendix

14. A method for diagnosing possible presence of gastritis in a human by evaluating a blood sample, comprising the steps of:

assaying the blood sample for the presence of antibodies specific for H,K-ATPase,

assaying the blood sample for the presence of antibodies specific for Helicobacter pylori,

assaying the blood sample for the concentration of pepsinogen I, and

comparing the presence of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen I concentration to the respective values of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen concentration of a normal population, and

further comprising the steps of multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies to get a number, and comparing the number to a number calculated similarly for the normal population.

wherein levels of H,K-ATPase antibodies, Helicobacter pylori antibodies, ~~and~~ pepsinogen I concentration in the sample and the number obtained by multiplying the level of pepsinogen I by the level of Helicobacter pylori antibodies that are different from the respective values in the normal population are indicative of gastritis.

15. The method according to claim 14, wherein the step of determining the levels of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen I, comprises performing immunoassays for detecting H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen I.

18. The method according to claim 14, wherein a lowered level of pepsinogen I concentration is indicative of corpus atrophy.

19. The method according to 14, wherein an increased level of pepsinogen I concentration is indicative of a corpus gastritis, without any autoimmunity involved.

20. The method according to claim 14, wherein a level of H,K-ATPase antibodies differing from that of the normal population is indicative of an autoimmune corpus atrophy.

21. The method according to claim 14, wherein a level of Helicobacter pylori antibodies differing from that of the normal population is indicative of antrum, or pangastritis.

22. The method according to claim 14, wherein increased levels of Helicobacter pylori antibodies, and normal to lowered concentrations of pepsinogen I are indicative of atrophy.

23. The method according to claim 14, wherein very low concentrations of pepsinogen I in combination with increased levels of H,K-ATPase antibodies are indicative of corpus atrophy.

24. The method according to claim 15, wherein measured levels of H,K-ATPase antibodies and Helicobacter pylori antibodies which are significantly higher than levels in a normal population are indicative of gastritis.

25. The method according to claim 15, wherein a lowered level of pepsinogen I concentration is indicative of corpus atrophy.

26. The method according to claim 15, wherein an increased level of pepsinogen I concentration is indicative of a corpus gastritis, without any autoimmunity involved.

27. The method according to claim 15, wherein a level of H,K-ATPase antibodies differing from that of the normal population is indicative of an autoimmune corpus atrophy.

28. The method according to claim 15, wherein a level of Helicobacter pylori antibodies differing from that of the normal population is indicative of antrum, or pangastritis.

29. The method according to claim 15, wherein increased levels of Helicobacter pylori antibodies, and normal to lowered concentrations of pepsinogen I are indicative of atrophy.

30. The method according to claim 15, wherein very low concentrations of pepsinogen I in combination with increased levels of H,K-ATPase antibodies are indicative of corpus atrophy.

32. The method according to claim 14, wherein measured levels of H,K-ATPase antibodies and Helicobacter pylori antibodies which are significantly higher than levels in a normal population are indicative of gastritis.

Evidence Appendix

None

Related Proceedings Appendix

None